

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

1-34. (Cancelled)

35. (Previously Amended) A method of delivering paclitaxel to an inner wall of a blood vessel of a patient from an implantable medical device having an expandable balloon with the paclitaxel on an outer surface of the balloon, the method comprising the steps of:

providing an angioplasty balloon having a dried layer containing the paclitaxel on the outer surface of the balloon, the balloon being free of a coating atop the dried layer, the balloon being free of a time-release layer, the balloon being free of a containment material and the balloon being free of a containment layer; and further wherein the balloon has folds, and portions of the dried layer containing paclitaxel are positioned in the folds;

advancing the balloon within the blood vessel to a treatment site within the blood vessel;

inflating the balloon at the treatment site to contact the balloon with an inner wall of the blood vessel;

maintaining the inflated balloon in contact with the inner wall of the blood vessel so as to transfer paclitaxel to the inner wall of the blood vessel;

deflating the balloon after said maintaining; and  
removing the deflated balloon from the blood vessel.

36. (Previously Presented) The method of Claim 35, wherein the balloon is inflated at the treatment site with an inflation time of up to about one minute.

37. (Cancelled)

38. (Previously Amended) The method of Claim 35, wherein the dried layer further comprises a diagnostic agent.

39. (Cancelled)

40. (Previously Amended) The method of Claim 35, wherein the blood vessel is a coronary artery.

41. (Previously Amended) The method of Claim 35, wherein at said providing step, the implantable medical device

includes a total of about 5 to about 500  $\mu\text{g}$  of the paclitaxel on the outer surface of the balloon.

42. (Previously Amended) The method of Claim 35, wherein the method is performed without implanting a stent within the blood vessel.

43. (Previously Presented) The method of Claim 35, wherein the balloon comprises a material selected from the group consisting of: a polyamide, polypropylene, PEBAX and polyethylene.

44. (Previously Amended) The method of Claim 35, wherein the dried layer consists essentially of about 5 to about 500  $\mu\text{g}$  of paclitaxel deposited on the outer surface of the expandable balloon.

45. (Cancelled)

46. (Previously Amended) The method of Claim 35, wherein the implantable medical device is a balloon catheter having an expandable balloon with about 0.2 to about 20  $\mu\text{g}$  of paclitaxel or a paclitaxel derivative deposited per  $\text{mm}^2$  of

the outer surface of the expandable balloon and a total of about 5 to about 500  $\mu\text{g}$  of the paclitaxel or the paclitaxel derivative deposited on the outer surface of the expandable balloon; and wherein the method further includes at least one of:

percutaneous insertion of the expandable balloon into the patient;

inflation of the balloon at the treatment site with an inflation time of up to about one minute to contact the paclitaxel or the paclitaxel derivative with the inner wall of the blood vessel; or

maintaining the outer surface of the inflated balloon in contact with the inner wall of the blood vessel for only the period of the inflation of the balloon.

47. (Previously Amended) The method of Claim 35, wherein the implantable medical device is a balloon catheter having an expandable balloon with a total of about 5 to about 500  $\mu\text{g}$  of paclitaxel or a paclitaxel derivative deposited on the outer surface of the expandable balloon;

the expandable balloon is percutaneously inserted into the patient;

the balloon is inflated at the treatment site with an inflation time of up to about one minute to contact the paclitaxel or paclitaxel derivative with the inner wall of the blood vessel; and

the outer surface of the inflated balloon is maintained in contact with the inner wall of the blood vessel for only the period of the inflation of the balloon.

48. (Previously Amended) The method of Claim 35, wherein at said providing step, the implantable medical device is a balloon catheter having an expandable balloon with a total of about 0.2 to about 20  $\mu\text{g}$  of paclitaxel or a paclitaxel derivative per  $\text{mm}^2$  of the outer surface of the expandable balloon.

49. (Previously Amended) A method of delivering paclitaxel to an inner wall of a blood vessel from a balloon catheter having an expandable balloon with a coating on an outer surface of the balloon, the method comprising:

providing a balloon catheter including a balloon with a dried coating consisting of paclitaxel or a mixture of paclitaxel with another bioactive agent, the dried coating

being free of any additional coating atop the dried coating, where the paclitaxel or mixture of paclitaxel with another bioactive agent is not incorporated within a containment layer, and where the balloon has folds and portions of the dried coating are positioned in the folds;

advancing the balloon within the blood vessel to a treatment site;

inflating the balloon to directly contact the paclitaxel or mixture of paclitaxel with another bioactive agent with an inner wall of the blood vessel; and

delivering the paclitaxel or mixture of paclitaxel with another bioactive agent to the inner wall of the blood vessel while maintaining the paclitaxel or mixture of paclitaxel with another bioactive agent in direct contact with the inner wall of the blood vessel while the balloon is inflated.

50. (Cancelled)

51. (Previously Presented) The method of Claim 49, where the balloon is attached to a catheter shaft that includes a guide wire lumen and an inflation lumen for inflating the balloon.

52. (Previously Amended) The method of Claim 49, where the paclitaxel or mixture of paclitaxel with another bioactive agent is brought into direct contact with the vessel wall only while the outer surface of the inflated balloon is maintained in contact with the inner wall of the blood vessel.

53. (Previously Amended) The method of Claim 52, where the method is performed without implanting a stent within the blood vessel.

54. (Previously Amended) A method of delivering paclitaxel to an interior wall of a blood vessel from a balloon catheter having an expandable balloon with a paclitaxel coating on an outer surface of the balloon, the method comprising:

providing a balloon catheter without a stent, the balloon catheter having a dried coating consisting of about 5 to about 500 micrograms of a single bioactive coating material consisting of paclitaxel per 25 mm<sup>2</sup> of the gross outer surface area of the balloon, the balloon catheter being free of any coating atop the paclitaxel, where the

paclitaxel is not incorporated within a containment layer and amounts of the paclitaxel are deliverable to the interior wall upon direct contact of the paclitaxel with the interior wall, and where the balloon has folds and amounts of the dried coating are positioned in the folds;

advancing the balloon within the blood vessel to a treatment site within the blood vessel;

inflating the balloon at the treatment site to directly contact the paclitaxel in the coating with the interior wall of the blood vessel and thereby deliver paclitaxel to the interior wall without implanting a stent within the blood vessel.

55. (New) The method of claim 35, wherein the folds are configured such that they unfurl upon inflation of the balloon, and wherein during said inflating the folds unfurl so as to cause portions of the balloon to come into rotational wiping contact with the inner wall of the blood vessel during which paclitaxel is transferred to the inner wall of the blood vessel.

56. (New) The method of claim 49, wherein the folds are configured such that they unfurl upon inflation of the



balloon, and wherein during said inflating the folds unfurl so as to cause portions of the balloon to come into rotational wiping contact with the inner wall of the blood vessel during which amounts of the paclitaxel or mixture of paclitaxel with another bioactive agent are transferred to the inner wall of the blood vessel.

57. (New) The method of claim 54, wherein the folds are configured such that they unfurl upon inflation of the balloon, and wherein during said inflating the folds unfurl so as to cause portions of the balloon to come into rotational wiping contact with the interior wall of the blood vessel during which paclitaxel is transferred to the interior wall of the blood vessel.

58. (New) A method of delivering paclitaxel to an inner wall of a blood vessel of a patient from an implantable medical device having an expandable balloon with the paclitaxel on an outer surface of the balloon, the method comprising the steps of:

providing an angioplasty balloon having a dried layer of coating material containing paclitaxel on the outer surface of the balloon, wherein the dried layer of coating

material is the only layer on the balloon, wherein the balloon has folds configured to unfurl upon inflation of the balloon, and wherein portions of the dried layer are positioned in the folds;

advancing the balloon within the blood vessel to a treatment site within the blood vessel;

inflating the balloon at the treatment site so as to cause the folds to unfurl so that portions of the balloon come into rotational wiping contact with the inner wall of the blood vessel during which amounts of the coating material containing paclitaxel are transferred to the inner wall of the blood vessel;

maintaining the inflated balloon in contact with the inner wall of the blood vessel;

deflating the balloon after said maintaining; and  
removing the deflated balloon from the blood vessel.

59. (New) The method of Claim 58, wherein the coating material further comprises a diagnostic agent.

60. (New) The method of claim 58, wherein the coating material consists essentially of paclitaxel.

61. (New) The method of claim 58, wherein the coating material further comprises an iodine-containing radiopaque agent.